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Indian Standard (Reaffirmed 2003)

SPECIFICATION FOR GLASS CONTAINERS FOR TRANSFUSION FLUIDS

(First Revision)

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MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
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Gr 4 *September* 1973

Indian Standard
SPECIFICATION FOR GLASS CONTAINERS FOR TRANSFUSION FLUIDS
(First Revision)

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SPECIFICATION FOR GLASS CONTAINERS FOR TRANSFUSION FLUIDS

(*First Revision*)

0. FOREWORD

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 12 February 1973, after the draft finalized by the Glassware Sectional Committee had been approved by the Chemical Division Council.

0.2 This standard was first published in 1965. The Sectional Committee responsible for the preparation of the standard decided to revise it with a view to, as far as possible, aligning it with ISO/R 1135-1969 ‘ Transfusion equipment for medical use’ issued by the International Organization for Standardization (ISO). In doing so neck finishes both with and without screw threads have been prescribed in this revision, besides an addition of neck size of 30’0 ± 0’5 mm. Further in keeping with the practices obtained in the field in this country, bottles of 300 and 1 000 ml nominal capacities have also been prescribed in this standard.

0.3 This standard contains clauses 3.3.1, 3.6.2, 3.9 and 4.2 which call for agreement between the purchaser and the supplier.

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS :2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes requirements and methods of sampling and test for glass containers for transfusion fluids, meant for use with transfusion equipment for medical use.

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*Ruler for rounding off numerical values (*revised*).

2. TERMINOLOGY

2.1 For the purpose of this standard the definitions given in IS :1382-1961*, in addition to the following, shall apply.

2.2 **Transfusion Equipment for Medical Use-Equipment** which is used to infuse human blood and its derivatives or other infusion fluids, but does not include syringes for injection and special mechanical devices.

3. REQUIREMENTS

3.1 Pattern- Transfusion bottles shall be of the pattern illustrated in Fig. 1.

3.2 **Material and Workmanship-The** bottles shall be transparent and substantially colourless. They shall be well annealed and have a smooth surface with no cracks or pinholes. They shall be substantially free from cords, bubbles, stones, seeds, mould-marks and other visible defects.

3.2.1 ***Limit of Alkalinity-When*** graded according to the method prescribed in 2 of IS: 2303-1963†, the bottles shall conform to Type 1 of the glass.

3.3 **Graduated Capacities-The** bottles shall be of graduated capacity of 500 ml (see Fig. 1B).

3.3.1 If agreed to between the purchaser and the supplier, the bottles may also be of graduated capacities of 300 ml and 1000 ml (see Fig. 1A and 1C).

3.4 External **Form of the Neck — The** bottles may be provided with a screw thread on the neck. Whether or not there is a screw thread, the neck shall be provided with a bead to permit the fitting of a cap to act either as the main closure or as an additional closure when the neck has a screw thread.

3.4.1 If a screw thread is provided, the overall diameter shall be less than that of the bead to facilitate the fitting of an additional closure (see figures in Tables 2 and 3).

3.5 Internal Neck Diameter — The nominal internal diameter of the neck shall be either 22·5 or 30 mm.

3.5.1 30 mm size shall be used as an alternative only for bottles having a graduated capacity of 500 ml.

3.6 Graduation Marks -There shall be two moulded scales marked at 100 ml intervals on the same side of the bottle. One scale shall read for the collection of fluid, the numbers being upright when the bottle stands on its base; the other scale shall serve for the delivery of fluid, the numbers being upright when the container is inverted. The marks shall not project more than 1 mm from the surface of the cylindrical portion of the bottle.

---

*Glossary of terms relating to glass industry.

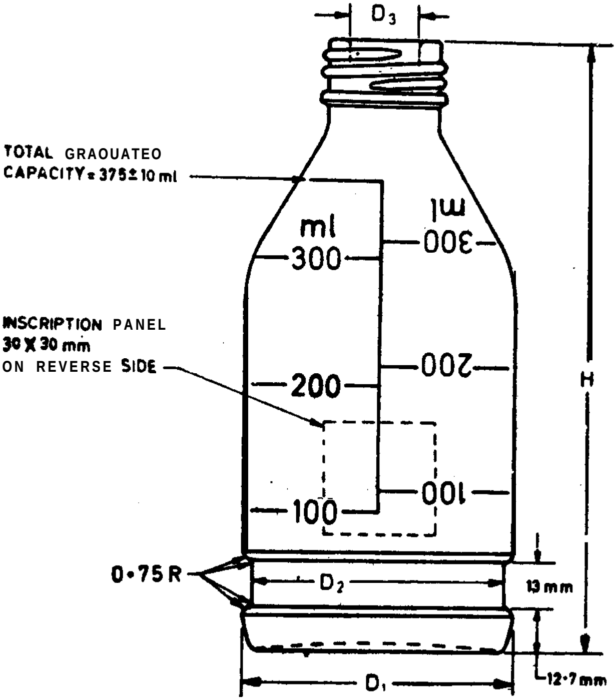
†Method of grading glass for alkalinity.

3.6.1 The tolerance on each graduation shall be ± 10 ml of the volume indicated.

3.6.2 If agreed to between the purchaser and the supplier, the bottles may be graduated additionally as follows:

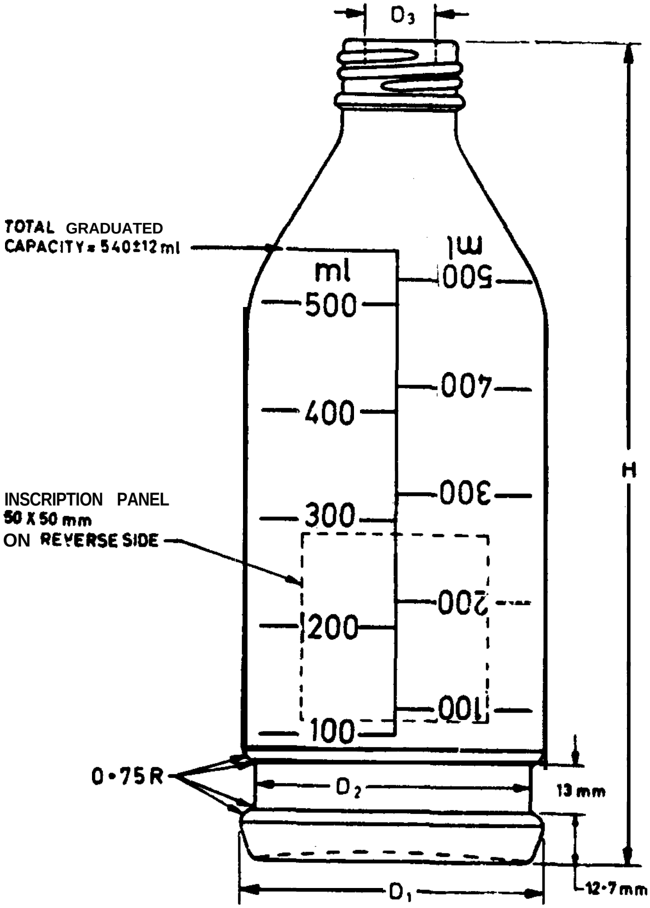
Graduated Capacity, ml	*Additional Graduations,* ml
300	350 and 375
500	540

3.6.3 The recommended patterns of graduations are given in Fig. 1A, 1B and 1C respectively for the three graduated capacities.


D₃
TOTAL GRADUATED CAPACITY = 375±10 ml
ml
300
200
100
ml
300
200
100
INSCRIPTION PANEL 30 X 30 mm ON REVERSE SIDE
0·75 R
D₂
13 mm
H
D₁
12·7 mm

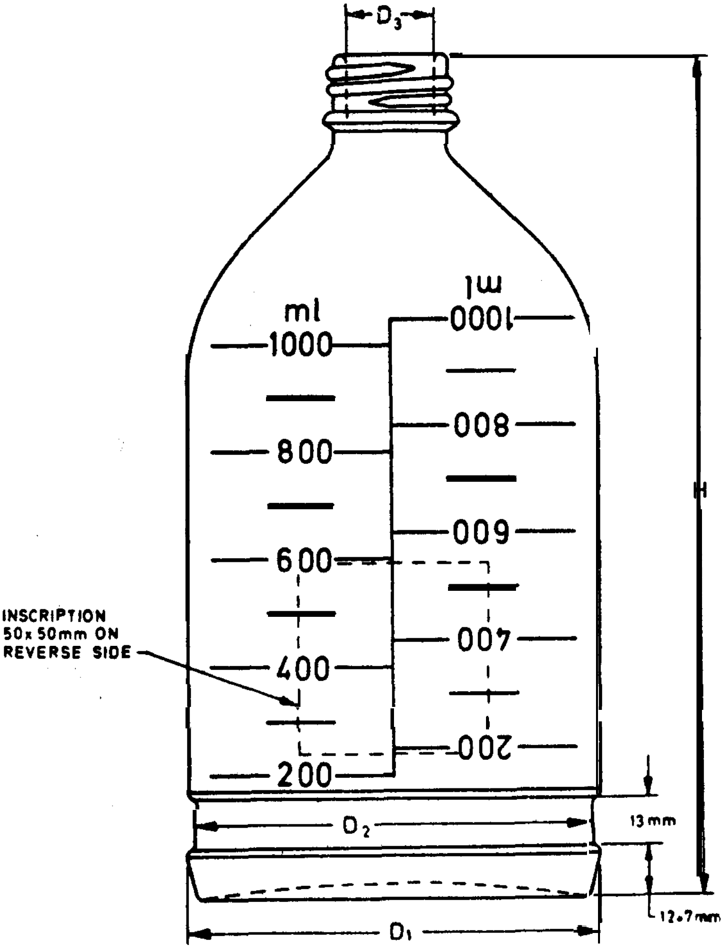
1A **Transfusion Bottle — 300-ml Capacity**

FIG. 1 ILLUSTRATION OF GLASS CONTAINERS FOR TRANSFUSION FLUIDS- *Contd*


D3
TOTAL GRADUATED CAPACITY = 540±12 ml
ml
500
400
300
200
100
INSCRIPTION PANEL 50 X 50 mm ON REVERSE SIDE
H
0·75R
D2
13 mm
12·7mm
D1

1B Transfusion Bottle — 500-ml Capacity

FIG. 1 ILLUSTRATION OF GLASS CONTAINERS FOR TRANSFUSION FLUIDS — *Contd*



1C Transfusion Bottle — 1000-ml Capacity

FIG. 1 ILLUSTRATION OF GLASS CONTAINERS FOR TRANSFUSION FLUIDS

3.7 Dimensions-The overall dimensions of bottles shall be as given in Table 1 read with Fig. 1.

TABLE 1 DIMENSIONS OF TRANSFUSION BOTTLES

SL No.	GRADUATED CAPACITY	INTERNAL NECK DIAMETER, D_3*	OVERALL HEIGHT, H, *Max*	OVERALL DIAMETER, D_1, *Max*	OVERALL DIAMETER, D, AT THE GROOVE, *Max*
(1)	(2)	(3)	(4)	(5)	(6)
	ml	mm	mm	mm	mm
i)	300	22.5 ± 0·5	166·5	73.5	70·5
ii)	500	22.5 ± 0·5	212.0	81.0	78.0
iii)	500	30.0 ± 0·5	153·0	91·5	88.5
iv)	1000	22.5 ± 0·5	213·0	108.5	105.5

*Corresponds to '*C*' in Tables 2 and 3.

3.7.1 *External Dimensions of the* Neck-The recommended dimensions of the bead and the screw threads (where provided) are as given in Tables 2 and 3 read with figures given in them.

3.8 **Thermal Resistance-The** bottles shall withstand without damage temperatures encountered during normal conditions of use including the following:

a) Subjecting the bottle to a pressure of $1\cdot4\ \text{kgf/cm}^2$ (or $1\cdot4\times10^7$ Pa) of saturated steam in an autoclave for 30 minutes after filling it up to the highest graduation mark and closing firmly;

or

Sterilizations of the empty bottles by autoclaving in saturated steam at temperatures up to 134°C for 1 hour;

b) Heating the empty bottle to a temperature of 260 ± 2°C, the rate of rise of temperature being not more than 5°C per minute; maintaining the bottle at 260 ± 2°C for 2 hours and then taking it out of the oven to allow it to cool to ambient temperature; and

c) Keeping the bottle at a temperature of − 40°C for 24 hours, after filling it to the highest graduation mark and tightening the closure fully with the rubber disc in position.

NOTE-The test at (c) is applicable only to containers meant for storing dried plasma.

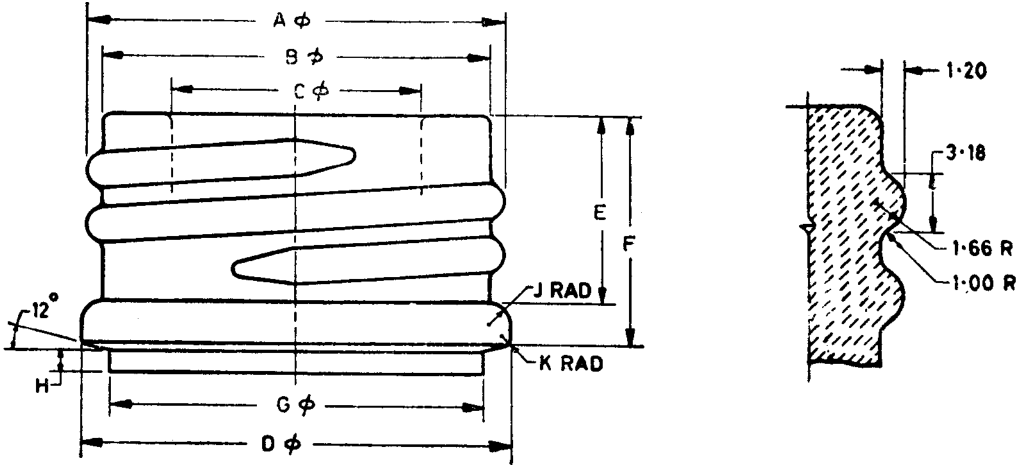
3.9 **Thermal Shock** Resistance-Transfusion bottles shall not break, crack or chip when subjected to a thermal shock (temperature difference as agreed to between the purchaser and the supplier but not less than 40°C) in accordance with Method A of IS : 6506-1972*.

***Methods for thermal shock test on glassware.**

TABLE 2 DETAILS OF ESTERKAL FORM AND DIMENSIONS OF 22·5-mm NECK PROVIDED WITH SCREW THREAD

(*Clause* 3.7.1)

All dimensions in millimetres.

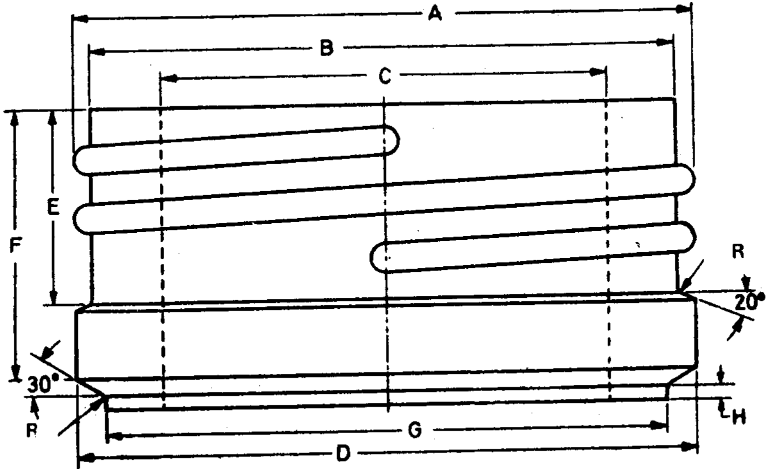


	A	*B*	*C*	*D*	*E*	*F*	G	*H*	*J*	*K*
Min	37·13	34·76	22·0	28.30	16.74	20.70	33.1	—	—	—
Max	37·64	35.26	23·0	38.81	17.00	21.20	34.3	2·0	1.98	0·40

TABLE 3 DETAILS OF EXTERNAL FORM AND DIMENSIONS OF 30-mm NECK PROVIDED WITH SCREW THREAD

(Clause 3.7.1)

All dimensions in millimetres.



	A	*B*	*C*	*D*	*E*	*F*	*G*	*H*	*R*
Min	41·6	39.3	29·6	41.6	12.8	17.6	—		—
Max	42.2	39·9	30.4	42.2	13·2	18.4	38.3	1·0	0·5

3.10 Resistance to Internal Pressure-The bottles when completely filled with water shall withstand an internal gauge pressure of not less than the following:

a) 10·3 bar (10·5 kgf/cm^2 or 10·5 x 10^7 Pa) for bottle with a 22·5-mm neck, and

b) 8·6 bar (8·8 kgf/cm^2 or 8·8 × 10^7 Pa) for bottle with a 30-mm neck.

The test pressure shall be reached in not more than 5 seconds and maintained for 1 minute.

3.11 **Mechanical Strength**-The bottle, charged with water to the total graduated capacity and immersed in water up to the highest graduation mark in a suitable centrifuge cup, shall withstand centrifuging, so as to produce an acceleration equivalent to 2 000 times that due to gravity in the plane of the base of the bottle for at least 30 minutes.

3.12 Inscription **Panel**-If required, a frosted panel may be provided on one side of the bottle immediately above the groove. The panel shall he 30 x 30 mm for 300-ml bottles and 50 x 50 mm for 500- and 1 000-ml bottles.

3.13 **Means of Suspension**-The bottles shall be provided with an external groove near the base to accommodate a metal band for suspending securely in an inverted position.

4. MARKING AND PACKING

4.1 **Marking**-The bottles shall be marked permanently at the base with the following:

a) Manufacturer's name or recognized trade-mark, if any; and

b) Year of. manufacture.

4.1.1 The bottles may also be marked with the ISI Certification Mark.

NOTE -The use of the IS1 Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The IS1 Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system ofinspection, testing and quality control which is devised and supervised by IS1 and operated by the producer. IS1 marked products are also continuously checked by IS1 for conformity to the standard as a further safeguard. Details of conditions under which a licence for the use of the IS1 Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

4.2 Packing-The bottles shall be packed as agreed to between the purchaser and the supplier.

5. SAMPLING

5.1 Representative samples of glass bottles shall be drawn and the criteria fur conformity determined as prescribed in Appendix A.

APPENDIX A

(*Clause* 5.1)

SAMPLING OF GLASS CONTAINERS FOR TRANSFUSION FLUIDS

A-1. SCALE OF SAMPLING

A-1.1 Lot-All the glass containers for transfusion fluids in a single consignment belonging to the same capacity and drawn from the same batch of manufacture shall constitute a lot.

A-1.2 Samples shall be tested from each lot to ascertain the conformity of containers in the lot to the requirements of this specification.

A-1.3 A sample of 58 containers shall be drawn at random from a lot. In case the lot size is less than 58, all the containers in the lot shall be drawn. Random number tables shall be used for drawing the samples. In case random number tables are not available, the samples shall be drawn in the manner given below:

> Starting from any container in the lot, count them as 1, 2, 3,.... etc, up to r in a systematic manner, where r is the integral part of $N/58$, N being the total number of containers in the lot. Every rth container thus counted shall be separated until 58 containers are obtained from the lot to give samples for test.

A-2. CRITERIA FOR CONFORMITY

A-2.1 The conformity of containers tested shall be judged as follows.

A-2.2 **Limit of Alkalinity**--Select at random two containers from the 58 selected under A-1.3 and test them according to 2 of IS : 2303-1963*. If the test result shows that the glass conforms to Type 1 for limit of alkalinity, then only the remaining samples shall be tested for conformity of the lot to other requirements given in this specification. If the test result fails to satisfy the requirement of limit of alkalinity, no further test need be done and the lot shall be rejected.

A-2.3 **Visual Inspection**-Every container in the sample shall be visually examined for workmanship (see 3.2) and all the containers in the sample shall satisfy the requirements of this specification.

A-2.4 **Dimensions and Nominal Capacity**-Tests for these characteristics shall be carried out in stages by taking 8 containers at each stage out of the total number 56 and a decision taken in accordance with the directions given in A-2.4.1 to A-2.4.10 read with Table 4. When a decision is reached after any stage of testing, further containers shall not be tested. In case the lot size is less than 56, all the containers shall be tested for the characteristics and defectives eliminated.

---

*Method of grading glass for alkalinity..

TABLE 4 CRITERIA OF JUDGMENT AT DIFFERENT STAGES OF TESTING

STAGE	SAMPLE SIZE	COMBINED TEST SAMPLING		
		Size	Acceptance No.	Rejection No.
(1)	(2)	(3)	(4)	(5)
First	8	8	*	2
Second	8	16	*	2
Third	8	24	0	2
Fourth	8	32	0	3
Fifth	8	40	1	3
Sixth	8	48	1	3
Seventh	8	56	2	3

*Acceptance not possible at this stage.

A-2.4.1 The first stage of testing shall constitute selection of 8 containers at random from the total number of 56 and testing them individually.

A-2.4.2 The lot shall not be accepted at the first stage even if there are no defective containers without further testing.

A-2.4.3 If the number of defective containers found is greater than or equal to the corresponding rejection number (which is 2 at the first stage), the lot shall be rejected without further testing.

A-2.4.4 If the number of defective containers found is less than 2, that is, 0 or 1, proceed to the second stage and draw another 8 containers at random from the remaining 48. Examine them and note the number of defectives. Add this number to the defectives, if any, found at the first stage to obtain the total number of defectives.

A-2.4.5 The lot shall not be accepted at the second stage also even if there are no defectives without further testing.

A-2.4.6 If the total number of defectives found at the first and second stages together is greater than or equal to the corresponding rejection number (which is 2 at the second stage) the lot shall be rejected without further testing.

A-2.4.7 If the number of defective containers found at the first and second stages together is less than 2, that is, 0 or 1, proceed to the third stage and draw another 8 containers at random from the remaining 40. Examine them and note the number of defectives. Add this number to the defectives, if any, found at the first and second stages to obtain the total number of defectives.

A-2.4.8 If the total number of defective containers found in the three stages is less than or equal to the acceptance number (which is 0 at the third stage), the lot shall be accepted without further testing.

A-2.4.9 If the total number of defective containers found at the first, second and third stages together is greater than or equal to the corresponding rejection number (which is 2 at the third stage), the lot shall be rejected without further testing.

A-2.4.10 If the total number of defective containers found is between the acceptance number (0) and the rejection number (2) at the third stage, that is 1, proceed to the fourth stage and apply the same method. If no decision is arrived at, continue to the fifth, sixth and then to the seventh stage till a decision is reached.

A-2.5 **Thermal Resistance, Thermal Shock Resistance and Mechanical Strength-The** lot which has been found to be satisfactory in accordance with A-2.4 shall be examined for ascertaining its conformity to the requirements of thermal resistance, thermal shock resistance and mechanical strength. For this purpose, **24** containers, from those already drawn and found satisfactory, shall be randomly selected. In case only **24** containers had been drawn under A-2.4, all of them shall be selected. These 24 containers shall then be divided into three groups of 8 containers each. Each of these groups of containers shall be separately tested for thermal resistance, thermal shock resistance and mechanical strength.

A-2.5.1 The lot shall be deemed as having satisfied the requirements of these characteristics, if no defective container is found in the sample.

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